H0045 01 - High Priority Medical Device Alert

Medical Device Ongoing Action
Updated: July 23, 2009
UMDNS Terms:
- Incubator/Radiant Warming Units, Infant, Mobile [18857]
- Warming Units, Patient, Radiant, Infant, Mobile [17433]

Suggested Distribution:
- Clinical/Biomedical Engineering
- Nursery
- Nursing
- Obstetrics/Gynecology /Labor and Delivery
- Pediatrics
- Risk Management/Continuous Quality Improvement
- Staff Education
- NICU

Geographic Regions:
- Brazil
- Canada
- China
- Dominican Republic
- France
- Korea
- Lebanon
- Mexico
- Nigeria
- Panama
- Poland
- Saudi Arabia
- Taiwan
- Turkey
- Uruguay
- U.K.
- U.S.
- Venezuela

Draeger Initiates Recall of Stabilet Infant Radiant Warmers in Response to Fire Hazard

Product Identifier:
Infant Radiant Warmers *[Capital Equipment]*

Manufacturers:	Models:
Borning	Stabilet 200
	Stabilet 300
Draeger	Not applicable*
Hill-Rom	1250
	1500
	2000
	2000/3000
	2200/3200
	3000
	3200

Hill-Rom model numbers may be followed by A, B, or C. Some of the models may also carry the original model name of "Stabilet." The manufacture of these devices was discontinued in 1998.

*In June 2004, Draeger Medical Infant Care purchased this product line from Hill-Rom.

Manufacturer: Borning [defunct]; Draeger Medical Inc [371341], 3135 Quarry Rd, Telford, PA 18969, United States; Hill-Rom Co Inc A Hillenbrand Industry [101318], 1069 State Rt 46 E, Batesville, IN 47006-9164, United States

Summary: Draeger has initiated a voluntary recall of the above infant radiant warmers. Until the units are removed from service, the company recommends limiting their use to patients not receiving oxygen therapy.

Problem: In a July 2009 Urgent Medical Device Recall Notification letter, Draeger states that an incident occurred on January 22, 2008, in which a brief, intense fire in the neonatal unit of a Minnesota hospital injured a full-term infant. At the time of the fire, the infant was in a bassinet beneath a Hill-Rom Stabilet 1250 Infant Radiant Warmer while receiving supplemental O_2. An independent investigation conducted by multiple expert parties (of which ECRI Institute was 1; for further information, including access to the Executive Summary of the investigation report, see Hazard Report Accession No. H0045) concluded that the fire was likely caused by a hot particle originating from the materials used in the warmer heater element assembly falling into the O_2-enriched environment near the infant's head. If this problem occurs, it may result in serious injury to the patient and/or caregiver.

Action Needed: Verify that you have received the July 2009 Urgent Medical Device Recall Notification letter from Draeger. Identify any affected product in your inventory. Draeger agrees with the following recommendations made by ECRI Institute in Hazard Report Accession No. H0045:

(1) Hospitals should immediately begin planning to remove the referenced models from service:

(a) Hospitals with a sufficient number of unaffected models to meet anticipated clinical needs should immediately remove the referenced warmers from service.

(b) Hospitals currently unable to provide required heating therapy if these units are removed from service should:

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- Begin budgeting for the replacement of the units; and
- Limit use of the referenced models to patients NOT requiring O_2 therapy, since O_2-enrichment may increase the risk of fire. Hospitals should inform all potential users of this restriction and clearly mark referenced units to reinforce this message.
- Use a different heating modality (e.g., an infant incubator) if an infant requires O_2 therapy (whether supplemental or via intubation) and no unaffected warmers are available.

(2) Once removed from service, the warmers should be rendered unusable by removing the heating element and the power cord. These warmers should not be used or sold for any other purpose.

Customers should report any problems to their appropriate regulatory agency.

For Further Information:			
Geographic Locations:	Contacts:	Telephone No.:	Web Site:
U.S.	Michael Kelhart	(800) 543-5047 (select option 1, then 2349#)	Click here
Outside the U.S.	Draeger local representative		

Source:

- Letter submitted by manufacturer.

Comment:

- This alert is a living document and may be updated when ECRI Institute receives additional information. In circumstances in which we determine that it is appropriate for customers to repeat their review of an issue (e.g., when additional affected product has been identified), we will post a separate update alert. In other cases, we may add information, such as additional commentary, recommendations, and/or source documents, to the original alert.
- During ECRI Institute's verification process, we discovered that the manufacturer's letter listed an incorrect model number. The correct information appears above.

Verification History: Action Confirmed by Mfr./Dist.[7/20/2009 11:05:55 AM]

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